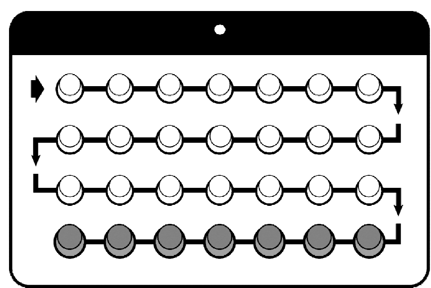
GUIDELINES FOR SERVICE PROVIDERS ON
USE OF THE COMBINED ORAL CONTRACEPTIVE (COC) PILL

1. Introduction



These guidelines are applicable to the Combined Oral Contraceptive (COC) pill which is being distributed by the National Family Planning Programme (Hospitals/Field clinics and Public Health Midwives).

The Combined Oral Contraceptive (COC) is a popular family planning method among a large number of women in Sri Lanka. The COC contains two hormones that are similar to the reproductive hormones (Oestrogen and Progesterone) which are naturally present in women.

Each packet of COC has 21 pills containing hormones and 7 pills containing iron (placebo). Each pill contains 0.03 mg of Ethinylestrodiol and 0.15 mg of Levonorgestrel.

2. How is pregnancy prevented by using the COC?

Primarily by preventing ovulation. When a woman uses COC continuously, the Oestrogen and Progesterone level in the blood increases above the normal concentration and gives rise to this effect.

3. What is the success rate of the COC?

- If used correctly according to instructions the success rate is more than 99% (i.e. less than one out of hundred COC uses has a risk of becoming pregnant).

Important :

- To ensure maximum effectiveness, the COC must be taken daily at a regular time, preferably at night after dinner.
- When women do not use COCs correctly the hormone concentration in the blood goes down and they could be exposed to the risk of becoming pregnant.

4. For whom is it most suitable?

i) for women who are newly married and needs to postpone their first pregnancy

ii) for women who want to space their children

iii) for women who want to limit their children and who do not like to have a permanent method

iv) for women who faces the risk of becoming pregnant (E.g. married, widowed, separated from husband)

5. When can a woman start taking the COC?

5.1	**For a woman who is menstruating**	
	5.1.1 Within first five days of the menstrual cycle	• A woman can start taking the COC immediately. It is not necessary to use another family planning method.
	5.1.2 After first five days of the menstrual cycle	• If pregnancy can be excluded (refer annexure) a woman can start taking the COC on any day. • Also, advice should be given to use an additional FP method (e.g. use of condom) or to avoid sexual contact for the next 7 days.
5.2	**For a woman who is not menstruating**	• If pregnancy can be excluded (refer annexure) a woman can start taking the COC on any day. • Also, advice should be given to use an additional FP method (e.g. use of condom) or to avoid sexual contact for the next 7 days.
5.3	**For a woman who is *breastfeeding* after delivery**	
	5.3.1 Within the first 6 months of delivery	• COC can have an effect on the quantity and quality of breast milk and therefore should not be taken within the first six months after delivery. N.B. A breast feeding mother can very rarely ovulate even though she is not menstruating. Therefore, she should use another suitable family planning method six weeks after the delivery.
	5.3.2 After 6 months of delivery	• Refer instructions in section 5.1. and 5.2

5.4	**For a woman who is *not* breastfeeding after delivery of a live birth, still birth or a neonatal death**	• As there is a risk of blood clot formation the COC should be avoided for the first 4 weeks. • After the first four weeks COC can be started immediately. It is not necessary to use another family planning method. • If the COC is going to be started at a later day (refer instructions in section 5.1. and 5.2).
5.5	**For a woman who has had an abortion (before 28 weeks of gestation)**	• COC can be started within the first 7 days after the abortion. It is not necessary to use another family planning method. • After seven days, refer instructions in section 5.1. and 5.2
5.6	**When changing over to the COC from another method containing hormones** 5.6.1 From a hormonal injection (DMPA) 5.6.2 From a hormonal implant	• She should commence taking the COCs on the day her next injection is due. It is not necessary to use another family planning method. • COC should be commenced on the day of the removal of implant. It is not necessary to use another family planning method. • If the COC cannot be commenced as instructed, refer instructions in section 5.1 and 5.2.
5.7	**When changing over to the COC from an (IUD)** 5.7.1 Within the first 5 days of the menstrual cycle	• The COC can be commenced while the IUD is in situ. It is not necessary to use another family planning method. • The IUD can also be removed at the same time.
	5.7.2 After the first 5 days of the menstrual cycle	• She can start on the COC, but the IUD should be removed during the next menstrual period.

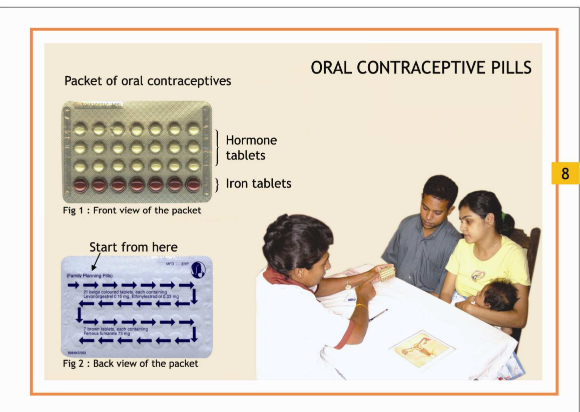
5.8	**When changing over to COC from a family planning method not containing hormones (natural methods or condoms)**	• Refer instructions in section 5.1 and 5.2.

N.B. A woman may have an increased tendency towards blood clotting during the first 4 weeks after a delivery. Therefore, COCs **should not be taken for whatever the reason** during the first 4 weeks of the post partum period.

6. Method of taking the pills

i) In a pill packet, the first pill out of the 21 hormone pills (tablets) should be taken within the first five days of the menstrual cycle.

ii) Thereafter one pill should be taken daily, continuously, at the same time of the day (following the directions of arrows) until all the pills in the packet are over (including the pills containing iron). Taking the pill at night, after dinner is more suitable as it minimises side effects.



iii) When one packet of pills is over, the following day pills from a new packet should be taken and the same instructions should be followed as above. Therefore, it is important to always have additional pill packets at hand.

- Menstruation usually takes place at the time when the iron containing pills are taken. Very rarely even after the completion of the pills in the first packet, bleeding may not occur.

- If it is certain that the pills were taken daily without a break, start on the second packet and continue as before. If there is no bleeding even after the completion of the second packet of pills seek medical advice.

To achieve maximum effectiveness with this family planning method, the pills should be taken daily and continuously without a break.

7. What advice should be given if the client missed taking the pills?

7.1	**If the client has missed 1 or 2 hormone pills on consecutive days or** **Started a new pack 1 or 2 days late**	• Take a hormonal pill as soon as possible. • Also, the pill scheduled for that day should be taken at the usual time i.e. at night (Two pills could be taken at the same time on the same day). • Thereafter, keep taking pills as usual, one each day. • It is *not* necessary to use another family planning (FP) method.
7.2	**If the client has missed 3 or more pills on consecutive days** **or** **Started a new pack 3 or more days late**	• Take a hormonal pill as soon as possible. • Also, the pill scheduled for that day should be taken at the usual time i.e. at night (Two pills could be taken at the same time on the same day). • Thereafter, keep taking pills as usual, one each day. • Also, Use an additional family planning method (e.g. use of condoms) or avoid sexual contact for the next 7 days.
	7.2.1 If the client has missed 3 or more pills from the first rows	• If the client has had unprotected sex, In addition, to the above instructions consider providing Emergency Contraceptive Pills (ECP) or inserting an IUD.
	7.2.2 If the client has missed 3 or more pills in the third row	• In addition, to the instructions in section 7.2 • Take the remaining hormonal pills in the current pack, discard iron containing pills and start a new pack the next day.
7.3	**If the client has missed taking the pills containing iron** (last 7 pills in the pack)	• Discard the missed pills. • Thereafter, keep taking iron pills as usual, one each day. • Commence on a new packet once all the iron pills are over.
7.4	**If the client has developed Severe vomiting and diarrhoea**	• If vomiting occurs within 2 hours of taking the pill its effectiveness is lost. Therefore, an additional pill should be taken once the vomiting is over.

		• Thereafter, keep taking pills as usual, one each day. • If vomiting or diarrhoea lasts for 3 or more days refer instructions in section 7.2.

8. Can the COC be used for a long period?

- If there are no risk factors the COC can be used continuously for a long period (even until menopause)

9. How long does it take to return to fertility after stopping the COC?

- Fertility is restored without delay.
- COC does not cause Subfertility.

10. Side Effects

- Minor side effects may occur with COC use (e.g. headache, dizziness, nausea, breast tenderness, weight changes, mood changes, acne and changes in vaginal bleeding patterns)

- These side effects usually wane off after the first pill packet is over. Therefore, it is important to ***explain clearly*** to the client that the side effects can be minimized by taking the pill after dinner and it is not necessary to stop the pill.

- If side effects persist, medical advice should be obtained.

10.1 Management of common side effects

The client should be advised to continue taking pills. Skipping pills risks pregnancy and can make some side effects worse.

- **Headaches**- suggest taking Paracetamol (500-1000mg) or other pain reliever

- **Nausea and dizziness**- Suggest taking pills at bed time or with food.

- **Breast tenderness**- Recommend that she wears a supportive bra, try hot or cold compresses or taking Paracetamol (500-1000mg) or other pain reliever

- **Weight changes**- Review diet and counsel as needed.

- **Mood changes**- Consider local remedies and give her support as appropriate.

- **Acne**- Usually improves with COC use. If not consider local remedies.

- **Changes in bleeding patterns**- Reassure. It is not harmful and usually becomes less or stops after the first few months of use. NSAIDS provides some relief. If

bleeding continues for more than one month refer to a Consultant Obstetrician and Gynaecologist for further management.

11. Absolute contraindications for the COC

Pregnancy and post partum period	• Pregnancy or suspicion of pregnancy. • When exclusively breast feeding, up to six months post partum. • If not breast feeding, until four weeks post partum (E.g.- still birth, neonatal death)
Diseases of the heart and the circulatory system	• Women having multiple risk factors for cardiac diseases (E.g.- Over 35 years of age, smoking, diabetes and hypertension – Having more than one of the above) • Blood pressure more than 140/90 mm of Hg • Current and past history of Ischaemic heart disease • Complicated heart valve disease • History of Stroke • Current and past history of Deep Vein Thrombosis-DVT & Pulmonary embolism-PE
Surgeries	• Major surgical operations requiring prolong immobilization (i.e. more than two weeks) or surgical procedures performed on the legs
Headache	• Migraine
Breast tumours	• Current or past history of breast cancer
Diabetes	• Diabetes with complications (retinopathy, neuropathy, nephropathy) • Diabetes for more than 20 years
Disease conditions of gall bladder/liver	• Current or past gall bladder diseases • Current liver disease (acute hepatitis) • Cancer of the liver • Severe cirrhoses of the liver
Drugs	• Treatment with Rifampicin for tuberculosis or leprosy • Using anti-epileptic drugs other than Sodium Valproate

For further information refer to *WHO Medical Eligibility Criteria Wheel for Contraceptive Use (adapted for Sri Lanka) 2009*

- Advice should be given to stop COC therapy 02 weeks before a major surgical operations or surgical procedures performed on the legs.
- After such surgical operation COC should be started 02 weeks after mobilization.
- If needed, advice on another family planning method during the period COC is not used.

12. Conditions when the COC should be stopped immediately.

- Migraine
- Severe chest pain
- Severe abdominal pain
- Severe pain in the leg muscles with suspicion of Deep Vein Thrombosis
- Jaundice

If a woman on oral contraceptive pills develop any of the above mentioned symptoms she should be referred immediately to hospital for medical treatment.

13. When providing COC the service providers should pay attention to the following

- Clients along with the spouse should be well counselled by using the tool 'Flash cards for family planning counselling'. Good counselling will help to minimise discontinuation of a method.

- The service provider should be friendly and courteous towards the client/couple. The client/couple should feel free to ask any questions and clear any doubts regarding the family planning method.

- Information on benefits, mild side effects (menstrual irregularities), where to get the next COC packet etc. should be provided.

- Confidentiality should be maintained. The client's decision to use COC should be an informed and independent choice.

- Before providing the client with COC, the service provider (e.g. Public Health Midwife - PHM) should use the following check list to assess the client's suitability.

Check list for Oral Contraceptive Pills

	DO YOU	YES	NO
1.	Think you are pregnant?		
2.	Breast feed an infant below 6 months?		
3.	Have high blood pressure?		
4.	Have /had a stroke, heart disease or blood clots in legs or other organ?		
5.	Have swelling of the calf muscles accompanied by pain?		
6.	Hope to undergo any major surgery or surgery in the legs?		
7.	Suffer from severe headaches frequently?		
8.	Have any breast lumps?		
9.	Have Diabetes?		
10.	Have/had gall bladder disease or any liver diseases (E.g. Hepatitis)?		

11.	Take medication for epilepsy, tuberculosis or leprosy?		

If '*Yes*' is the answer to one or more questions it is advisable to counsel her to use another family planning method or refer the client to a Medical Officer with medical records if available.

Advice to the Medical Officer:
Check whether the client is eligible to use COC [refer to *WHO Medical Eligibility Criteria Wheel for Contraceptive Use (adapted for Sri Lanka) 2009*] or counsel client to use another suitable FP method.

If the client is eligible to use the COC according to the check list;

i) Take steps to supply her with adequate number of COCs (3 packets on the first issue). Advice client to keep an extra packet at all times.

ii) Very clear instructions must be given to the client on
   a) Using COC
   b) missed pills
   c) situations when the COC should be immediately stopped

iii) The client should be informed that she should obtain a new packet before the current packet of pills is over.

iv) Whenever there is a problem or when there is a need to change over to another FP method the client should be advised to meet the service provider immediately.

v) Clients should be advised to store the pill packet in a cool, dry place, out of reach of children.

N.B.
Inconsistent and incorrect use of COC may lead to ***unexpected pregnancies***. Therefore, clients who are at risk of missing pills may consider using another FP method.

Also, it is suitable to counsel and provide clients with ***condoms***, for use in the following situations:

- Until COCs are started
- If the client has to stop or misses the COC due to some reason
- If the COC packet is started late
- In situations where the client or her husband is having or has the risk of having AIDS or any other sexually transmitted disease.

14. Follow up

The purpose of follow up should be to address any problems/queries that the clients may encounter and encourage continuity of use.

14.1 In the Field

- PHM must visit the client at home once a month and provide her with a packet of COC (2-3 packets if necessary).
- Inquire whether the pills are taken correctly and continuously.
- Inquire regards side effects, give necessary advice or refer.
- Record relevant details in the FP Field Record (H-1154) & FP Client Record (H-1155)

14.2 In the Clinic

- Clients continuing COC should have an annual medical examination to identify any risk conditions such as hypertension, diabetes etc.
- If any side effects have occurred they must be entered in the Family Planning Clinic Record (H-1153). Side effects should be managed as mentioned in section 10.1.

15. Service Provision

15.1 Service Providers

- Medical Officers
- Registered Medical Officers (RMO)
- Public Health Nursing Sisters (PHNS)
- Supervising Public Health Midwives (SPHM)
- Public Health Midwives (PHM)

15.2 Places where the COC is available

- Government Family Planning Clinics (Hospitals, MOH Offices and Field FP clinics)
- Office of the Public Health Midwife
- Estate Family Planning Clinics
- FP clinics conducted by Non Governmental Organizations (E.g. FPA, PSL, SLAVSC)
- Private hospitals and private medical centres
- Franchised Pharmacies

15.3 Storage

- Packets containing COC should be kept at room temperature (15-30^{0}C) in a cool, dry place, away from direct sunlight.

References:

1. Family Planning a Global for Providers, WHO, USAID, JHBSPH, 2008
2. Medical Eligibility Criteria Wheel for Contraceptive Use, WHO, Third Edition, 2004.
3. Medical Eligibility Criteria Wheel for Contraceptive Use, WHO, 2008 Update
4. British National Formulary, 2006.

ANNEXURE

How can the service provider be satisfied that a woman is not pregnant?

The service provider can be satisfied that the woman is not pregnant, if the woman does not have any signs and symptoms of pregnancy and she is in any situation that is listed below.

1. When sexual contact has not taken place after the last regular menstrual period
2. When a family planning method was used correctly and continuously
3. Within the first 7 days of menstruation
4. Within the first 7 days after an abortion
5. Within the first 4 weeks post partum
6. Within 6 months of the delivery, menstruation has not commenced, and the woman is exclusively breast feeding the baby
7. If the client does not fit into any of the above criteria advice her not to have any unprotected sexual contact for 3 weeks and confirm non pregnancy state by doing a urine test for pregnancy.

	Early signs & symptoms of pregnancy	**Later signs & symptoms of pregnancy**
1.	Delayed menstrual periods	Larger breasts
2.	Nausea/ Vomiting	Darker nipples
3.	Recent breast tenderness/fullness	Increased vaginal discharge
4.	Increased urine frequency	Enlarged abdomen
5.	Changed eating habits	Movements of baby
6.	Weight changes	
7.	Mood changes	

- It is not always necessary to do a urine test to diagnose pregnancy.
- Furthermore, pregnancy cannot be diagnosed by a urine test until about five weeks after the last menstrual periods.